K954610

Intermedics Inc.
A company of SULZER medica

DEC 16 1996

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

Submitter's Name: Intermedics, Inc.
4000 Technology Drive
Angleton, TX 77515 USA
Telephone: (409) 848-4525
Contact Person: Alan D. Totah, Director of Domestic Regulatory Affairs

Date of Summary: December 6, 1996

Device Names: Model 430-07 Endocardial Pacing Lead
Model 431-07 Endocardial Pacing Lead
Model 432-03 Endocardial Pacing Lead
Model 433-03 Endocardial Pacing Lead

Legally Marketed Devices To Which Equivalence Is Claimed: The Intermedics Models 430-07 and 432-03 Endocardial Pacing Leads.

The Intermedics lead models which are the subject of this 510(k) Notification are legally marketed devices. This 510(k) Notification is submitted to provide data and evidence to support labeling claims concerning the low threshold performance of the iridium oxide-coated (IROX™) titanium tip electrode. In this submission, the Models 430-07 and 432-03 Endocardial Pacing Leads are considered the legally marketed predicate devices since these models were employed in the clinical study which yielded the low threshold data in humans. Since the IROX tip electrode is identical among all lead models in design, materials and construction, the clinical data gathered on the performance of the Model 430-07 and 432-03 Leads are directly applicable to the performance of the other lead models, and the claims concerning low threshold performance are therefore made for all lead models.

New Performance Claim: This 510(k) Notification is submitted to provide data and evidence to support the following labeling claim concerning the low threshold performance of the iridium oxide-coated (IROX) titanium tip electrode:

> The mean stimulation threshold, both acute and chronic, is equal to or less than 0.38 millisecond at a pulse amplitude of 1.5 volts, with a 97.5 percent confidence limit.

Device Description: The Intermedics Model 430-07, 431-07, 432-03, and 433-03 Endocardial Pacing Leads are designed for use with implantable cardiac pulse generators for long-term cardiac pacing. Passed transvenously through the cephalic, subclavian, or jugular

vein (external or internal), the tip electrode (cathode) is positioned at the endocardial surface to permit contact with the heart. The tip fixation mechanism consists of four silicone rubber tines. The lead body, which consists of insulated conductor coils, carries electrical impulses from the heart to the pulse generator, resulting in sensing. The lead body also carries impulses from the pulse generator to the endocardial surface, causing cardiac depolarization (pacing). The proximal end of the lead is connected to the header of the implanted pulse generator.

The electrodes of the Intermedics Model 430-07, 431-07, 432-03, and 433-03 Endocardial Pacing Leads are made of titanium coated with iridium oxide (IROX™). Clinical trials with the Models 430-07 and 432-03 IROX endocardial pacing leads through twelve months demonstrated low threshold performance: 1.5 volts at or below 0.38 millisecond pulse width, with 97.5% confidence.

Intended Use: The Intermedics leads which are the subject of this 510(k) Notification are endocardial pacing leads designed for use with implantable pulse generators for long-term cardiac pacing. This indication is identical to the indication for use of the legally marketed predicate devices, the Intermedics Models 430-07 and 432-03 Endocardial Pacing Leads.

The indications for ventricular pacing include, but are not limited to: sick sinus syndrome, sinus bradycardia, complete heart block, symptomatic second-degree heart block, and certain conditions of asymptomatic second-degree block. In the presence of normal atrioventricular (A-V) conduction, the indications for atrial pacing include, but are not limited to: sinus arrest, sick sinus syndrome, sinus bradycardia and conditions requiring increased cardiac efficiency, enhanced cardiac output or the overdrive of certain cardiac arrhythmias. In the absence of normal A-V conduction, an atrial lead may be used with a ventricular lead in a dual-chamber pacing system to restore A-V synchrony.

Descriptive Summary Of Technological Characteristics And Those Of Predicate Devices: Following is a summary of the technological characteristics of the Models 430-07 and 432-03 Endocardial Pacing Leads (predicate devices) and those of the other lead models which are the subject of this 510(k) Notification:

- The **Model 430-07** is a bipolar lead, designed for use in the ventricle.
- The **Model 431-07** is a unipolar lead, designed for use in the ventricle.
- The **Model 432-03** is a bipolar lead, designed for use in the atrium.
- The **Model 433-03** is a unipolar lead, designed for use in the atrium.

All these leads have the same tip electrode, identical in design (slotted blunt tip), materials (titanium coated with iridium oxide), and construction. The differences among the lead models do not pertain to new indications for use nor to new technological characteristics. These differences pertain only to the polarity of the lead and to the heart chamber in which the lead is implanted. The differences among the lead models do not affect the safety and effectiveness of the devices, nor do they affect the performance claim which is the subject of this 510(k) Notification.

Performance Data: Animal and human clinical performance data, acute and chronic, have been gathered on Intermedics Endocardial Pacing Leads with iridium oxide-coated titanium tip electrodes.

Animal Study

In order to evaluate the electrical performance of new electrode technologies, Intermedics conducted a long-term animal study of endocardial leads. Twenty-four leads were implanted in twelve dogs. All leads were unipolar, 5 French lead body, polyurethane insulated tined leads. Eight of each of the following leads were used in the study:

- Biopore™ Leads ("Biopore"), with a carbon-coated porous titanium electrode;
- IROX™ Leads ("IROX"), with an iridium oxide-coated titanium electrode; and
- IROX™ Leads ("IROX-PEG"), with an iridium oxide-coated titanium electrode layered with a thin coating of polyethylene glycol (PEG).

Stimulation thresholds were measured at regular intervals for 24 weeks. The IROX-PEG stimulation thresholds rose only 0.23 volts from implant to the chronic period (after week 6), and were significantly lower than those of Biopore and IROX. Low acute values were observed for all leads, but the IROX-PEG electrode demonstrated lower subchronic, peak and chronic values, with the mean pacing threshold less than 0.6 volts at 0.6 millisecond pulse width at 24 weeks. The data from this study establish the low threshold characteristics of the IROX-PEG electrode.

Clinical Study

Clinical performance data have been gathered on the Models 430-07 and 432-03 Endocardial Pacing Leads to support the performance claim of low acute and chronic stimulation threshold. Pacing threshold data were reported at implant, two weeks, four weeks, six weeks, three months, six months and twelve months. The data showed a mean pacing threshold of 0.32 millisecond in the ventricle and 0.35 millisecond in the atrium at 1.5 volts at the two-week follow-up point; this threshold gradually decreased to a mean value of 0.26 millisecond in both chambers at the six-month follow-up visit. Statistical analysis demonstrated that the dependence of capturing pulse width on pulse amplitude remains invariant with respect to time elapsed from implant. An upper confidence bound of 97.5% on the capturing pulse width was computed to be at or below 0.38 millisecond at a pulse amplitude of 1.5 volts.

The results of the clinical study establish the low threshold performance of the Models 430-07 and 432-03 Endocardial Pacing Leads on both an acute and a chronic basis, and support the low threshold labeling claim proposed by Intermedics.